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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,538	03/07/2002	Deb K. Chatterjee	0942.5250001	8240

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STERNE, KESSLER, GOLDSTEIN & FOX PLLC  
1100 NEW YORK AVENUE, N.W.  
WASHINGTON, DC 20005

EXAMINER
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PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/091,538

Applicant(s)

CHATTERJEE ET AL.

Examiner

Rebecca E. Prouty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 6-26, 28, 30-34, 36, 37, 39, 41-57 and 60-96 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 16, 17, 28, 30, 39, 41, 51-57, 60-62, 69, 70, 77, 78 and 85-96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/7/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2-4,6-15,18-26,31-34,36,37,43-50,62-68,71-76 and 79-84.

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Claims 5, 27, 29, 35, 38, 40, 58, and 59 have been canceled. Claims 1-4, 6-26, 28, 30-34, 36, 37, 39, 41-57, 60 and newly presented claims 61-96 are still at issue and are present for examination.

Claims 2-4, 6-15, 18-26, 31-34, 36, 37, and 43-50 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/4/04.

Applicant's election of *E. coli* having a mutation in recBCD (Exonuclease V) as the species of *E. coli* having a mutation that results in reduced activity of a nuclease in the reply filed on 8/2/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 62-68, 71-76 and 79-84 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/2/06. Therefore, claims 1, 16, 17, 28, 30, 39, 41, 51-57, 60-62, 69, 70, 77, 78, and 85-96 are examined herein.

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Claims 61, 69 and 77 are objected to because of the following informalities: "said nuclease in" in claims 61, 69 and 77 should be "said nuclease is". Appropriate correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 16, 17, 27, 28, 30, 35, 39, 41, 42, 51-60, 85, 88, 91, and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pratt (1984) in view of Yu et al. (Reference AR14 of applicant's IDS).

Pratt. teach *E. coli* coupled transcription/translation systems comprising an extract of an *E. coli* strain having a mutation in the *recB* gene (see pages 200-201) such that the extract exhibits a lack of the RecBCD exonuclease (also called

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exonuclease V) and a template DNA as well as several energy sources (i.e., ATP, GTP, and PEP). This transcription/translation is disclosed as particularly useful for linear DNA templates as these type of templates are particularly susceptible to degradation by the RecBCD exonuclease. Pratt however teach that these strains produce systems with high levels of background synthesis due to large amounts of contaminating chromosomal fragments or require an extended pre-incubation step (see pages 200-201).

Yu et al. teach that mutant *recBCD* strains have been used to prevent the rapid degradation of linear DNAs but that such strains lacking the RecBCD exonuclease are extremely poor growing. Yu et al. teach that one can alternatively inhibit the RecBCD exonuclease using the lambda phage Gam protein.

Therefore, it would have been obvious to one of ordinary skill in the art to replace the use of the *recB E. coli* strain used by Pratt et al. with a wild type *E. coli* strain (such as the MRE600 strain disclosed by Pratt as being the preferred strain for preparation of the S30) and to include the lambda phage Gam protein in the transcription/translation reaction to inhibit the degradation of linear template DNAs.

Applicants argue that production of the Gam protein within a genetic background including wild type production of the *E.*

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*coli* recBCD exonuclease is not recited in the claims as amended. Rather, the claims recite compositions that include an *E. coli* extract and Gam, in which the Gam is not expressed by the *E. coli* cell used to make the extract. However, it is noted that Gam is not an *E. coli* encoded protein at all and as such would not be part of the genetic background of a wild type *E. coli* strain such as the MRE600 strain disclosed by Pratt which the rejection suggested using. As such adding the Gam protein to a ITT system made from an extract of the MRE600 strain as suggested meets all limitations of the rejected claims.

Applicants argue that Pratt does not suggest solving the problems resulting from use of a recB mutant strain by using a recB inhibitor but instead by using the methods of Gold and Schweiger. However, the rejection is not made over Pratt alone but instead over the combination of Pratt and Yu et al. Yu et al. clearly teach a different approach to solving the inherent problems of use of recB mutant *E. coli* than that taught by Gold and Schweiger et al. Furthermore, as the use of a protein inhibitor of recB as taught by Yu et al. would be substantially simpler than the method of Gold and Schweiger et al., requiring merely the addition of a protein to the ITT extract, a skilled artisan would clearly have been motivated to use the approach taught by Yu et al.

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Claims 86, 87, 89, 90, 92, 93, 95, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pratt (1984) in view of Yu et al. (Reference AR14 of applicant's IDS) as applied to claims 1, 16, 17, 27, 28, 30, 35, 39, 41, 42, 51-60, 85, 88, 91, and 94 above, and further in view of Swartz et al. (WO 00/55353).

Pratt and Yu et al. are discussed above but do not specifically teach using 2 different energy sources selected from the group consisting of pyruvate, PEP, carbomyl phosphate, acetyl phosphate, creatine phosphate, phosphopyruvate, glyceraldehydes-3-phosphate and glucose-6-phosphate or particularly PEP and acetyl phosphate in the ITT system described.

Swartz et al. teach the alteration of the energy generation system of synthetic systems including the ITT systems described by Pratt et al. by replacing the PEP regeneration system with a system which regenerates acetyl phosphate or systems which include small amounts of secondary energy sources (e.g. acetyl phosphate, PEP and creatine phosphate in combination with pyruvate and pyruvate oxidase (see page 6)). As such it would have been obvious to one of ordinary skill in the art to substitute the energy generating systems of Pratt et al. with the systems disclosed by Swartz et al.



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Claims 61, 62, 69, 70, 77, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pratt (1984) in view of Yu et al. (Reference AR14 of applicant's IDS) as applied to claims 1, 16, 17, 27, 28, 30, 35, 39, 41, 42, 51-60, 85, 88, 91, and 94 above, and further in view of Kudlicki et al. (US Patent 6664,379).

Pratt and Yu et al. are discussed above and teach the use of extracts of the *E. coli* strain MRE600 in which the major RNase activity of *E. coli* is deleted but do not specifically teach using an extract of an *E. coli* strain deleted for one or more DNases.

Kudlicki et al. teach the inhibition of multiple RNases and DNases during synthetic reactions including ITT systems.

As Kudlicki et al teach the elimination of DNase activity as well as RNase activity during an ITT reaction is useful and as the genome of *E. coli* is known, it would have been obvious to one of ordinary skill in the art to delete the genes encoding one of more DNases of *E. coli* to reduce the DNase activity of the ITT extract.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Rebecca Prouty', is positioned above the printed name and title.

Rebecca Prouty  
Primary Examiner  
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